

Date: July 7, 2004



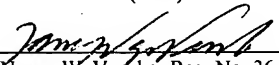
## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Merril et al.  
Appl. No. : 10/659,711  
Filed : September 11, 2003  
For : ANTIBACTERIAL THERAPY  
WITH BACTERIOPHAGE  
GENOTYPICALLY MODIFIED  
TO DELAY INACTIVATION  
BY THE HOST DEFENSE  
SYSTEM  
Examiner : Unknown  
Group Art Unit : 1646

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

July 7, 2004

(Date)

  
Nancy W. Vensko, Reg. No. 36,298

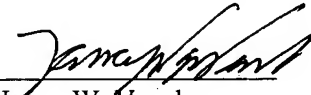
## TRANSMITTAL LETTER

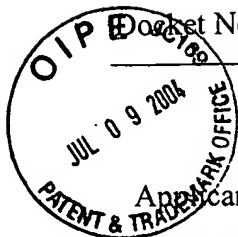
Mail Stop: Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement.
- (X) A PTO Form 1449 with forty-seven (47) references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

  
Nancy W. Vensko  
Registration No. 36,298  
Attorney of Record  
Customer No. 20,995  
(805) 547-5580

**INFORMATION DISCLOSURE STATEMENT**

Applicant : Merrill et al.  
App. No. : 10/659,711  
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For : ANTIBACTERIAL THERAPY WITH  
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Dear Sir:

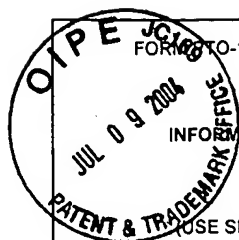
Enclosed is form PTO-1449 listing 47 references. Copies of disclosed U.S. patents and/or publications are not included pursuant to PTO waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(i) for applications filed after June 30, 2003. Copies of other references, if listed, are enclosed.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,  
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 7/7/04

By:   
Nancy W. Venske  
Registration No. 36,298  
Attorney of Record  
Customer No. 20,995  
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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

~~NIH2981DC1CC1~~

APPLICATION NO.

10/659,711

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT

Merril et al.

FILING DATE

September 11, 2003

GROUP

1645

1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1	4,332,897	06/01/1982	Nakano et al.			
	2	4,375,734	03/08/1983	Kozloff et al.			
	3	4,797,363	01/10/1989	Teodorescu et al.			
	4	4,865,979	09/12/1989	Nakano et al.			
	5	4,946,778	08/07/1990	Ladner et al.			
	6	5,132,221	06/21/1992	Ward et al.			
	7	5,168,037	12/01/1992	Entis et al.			
	8	5,284,934	02/08/1994	Allen, Jr.			
	9	5,344,822	09/06/1994	Levine et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
	10	Angel, M.F. et al. 1987 "Beneficial effects of staphage lysate in the treatment of chronic recurrent hidradenitis suppurativa," <i>Surgical Forum</i> 38:111-112.
	11	Audesirk, G. et al. 1986 <i>Biology Life on Earth</i> , Macmillan Publishing Company, N.Y. pp. 202-203.
	12	Bendinelli, M. et al. 1988 "Disruption of Phagosomal Membrane by the Virulent H37Rv Strain of <i>M. tuberculosis</i> " in: <i>Mycobacterium tuberculosis: Interactions With the Immune System</i> (Infectious Agents and Pathogenesis), Herman Friedman (Editor), Plenum Press, pp. 311-313.
	13	Berchieri, A. Jr. et al. 1991 "The activity in the chicken alimentary tract of bacteriophages lytic for <i>Salmonella typhimurium</i> ," <i>Res. Microbiol.</i> 142:541-549.
	14	Bogovazova, G.G. et al. 1992 "Immunobiological properties and therapeutic effectiveness of <i>Klebsiella</i> bacteriophages preparations," <i>Zh. Mikrobiol. Epidemiol. Immunobiol.</i> 3:30-33.
	15	Cislo, M. et al. 1987 "Bacteriophage treatment of suppurative skin infections." <i>Arch Immunol Ther Exp (Warsz)</i> 35:175-183.
	16	Engelstad, M. et al. 1992 "A constitutively expressed vaccinia gene encodes a 42-kDa glycoprotein related to complement control factors that forms part of the extracellular virus envelope." <i>Virology</i> 188:801-810.
	17	Frank, M.M. et al. 1992 "The Mechanism by which microorganisms avoid complement attack," <i>Curr. Opin. Immunol.</i> 4:14-19.
	18	Geier, M.R. et al. 1973 "Fate of bacteriophage Lambda in non-immune germ-free mice," <i>Nature</i> 246:221-222.

EXAMINER	DATE CONSIDERED
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.	

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. <del>NIH2981DC1CC1</del> <b>NIH298.1DC1CC1</b>	APPLICATION NO. 10/659,711
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Merril et al.	
		FILING DATE September 11, 2003	GROUP <del>1045</del> <b>1046</b>

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	19 Gherna, R., et al. 1992 <u>American Type Culture Collection Catalogue of Bacteria and Phages</u> , Eighteenth edition, pp. 402-409.
	20 Hidaka, Y. et al. 1991 "Glycoprotein C of herpes simplex virus type 1 is essential for the virus to evade antibody-independent complement-mediated virus inactivation and lysis of virus-infected cells" <i>J. Gen. Virol.</i> <b>72</b> :915-921.
	21 Isaacs, S.N. et al. 1992 "Characterization of a vaccinia virus-encoded 42-kilodalton class I membrane glycoprotein component of the extracellular virus envelope" <i>J. Virol.</i> <b>66</b> :7217-7224.
	22 Isaacs, S.N. et al., 1992 "Vaccinia virus complement-control protein prevents antibody-dependent complement-enhanced neutralization of infectivity and contributes to virulence" <i>PNAS USA</i> <b>89</b> :628-632.
	23 Jackson, R.J. et al. 2001 "Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox," <i>J. Virol.</i> <b>75</b> :1205-1210.
	24 Kress, D.W. et al. 1980 "A preliminary report on the use of staphage lysate for treatment of hidradenitis suppurativa," <i>Ann. Plastic Surgery</i> <b>6</b> :393-395.
	25 Kucharewicz-Krukowska, A. et al. 1987 "Immunogenic effect of bacteriophage in patients subjected to phage therapy." <i>Arch Immunol Ther Exp (Warsz)</i> . <b>35</b> :553-561.
	26 Lambris, J.D. et al. 1993 "Use of synthetic peptides in exploring and modifying complement reactivities." In <u>Activators and inhibitors of complement activation</u> . R.B. Sim, editor. Kluwer Academic Press, Lancaster. pp. 201-232.
	27 Mazacek, M. et al. 1969 "Die Bakteriophagie in der therapie und prophylaxe der infektionskrankheiten," <i>Zentralbl. Bakteriol.</i> <b>211</b> :385-394.
	28 Merrill, C.R. et al. (1996) "Long-circulating bacteriophage as antibacterial agents," <i>PNAS USA</i> <b>93</b> :3188-3192.
	29 Montefiori, D.C. et al. 1994 "Complement control proteins, CD46, CD55, and CD59, as common surface constituents of human and simian immunodeficiency viruses and possible targets for vaccine protection." <i>Virology</i> , <b>205</b> :82-92.
	30 Peake, P. et al. 1990 "Peptide inhibitors of C3 breakdown." <i>Clin. Exp. Immunol.</i> <b>79</b> :454-458.
	31 Peremitina, L.D. et al. 1981 "[Experience in the therapeutic use of bacteriophage preparations in suppurative surgical infections]" <i>Zh. Mikrobiol. Epidemiol. Immunobiol.</i> <b>9</b> :109-110.
	32 Roitt I.M. 1991 <u>Essential Immunology</u> , Seventh Edition, Blackwell Scientific Publications, pp. 110-113.
	33 Rother, R.P. et al. 1995 "Protection of retroviral vector particles in human blood through complement inhibition." <i>Human Gene Therapy</i> <b>6</b> :429-435.
	34 Salmon, G.G. Jr. et al. 1963 "Staphage lysate therapy in chronic staphylococcal infections," <i>J. Med. Soc. N. J.</i> <b>60</b> :188-193.
	35 Schasteen, C.S. et al., 1988 "Synthetic peptide inhibitors of complement serine proteases--II. Effects on hemolytic activity and production of C3a and C4a." <i>Molec. Immunol.</i> <b>25</b> :1269-1275.
	36 Slopek, S. et al. 1983 "Results of bacteriophage treatment of suppurative bacterial infections. I. General evaluation of the results." <i>Arch Immunol Ther Exp (Warsz)</i> <b>31</b> :267-291.
	37 Slopek, S. et al. 1983 "Results of bacteriophage treatment of suppurative bacterial infections. II. Detailed evaluation of the results." <i>Arch Immunol Ther Exp (Warsz)</i> <b>31</b> :293-297.
	38 Slopek, S. et al. 1984 "Results of bacteriophage treatment of suppurative bacterial infections. III. Detailed evaluation of the results obtained in further 150 cases." <i>Arch Immunol Ther Exp (Warsz)</i> <b>32</b> :317-335.
	39 Slopek, S. et al. 1985 "Results of bacteriophage treatment of suppurative bacterial infections. IV. Evaluation of the results obtained in 370 cases." <i>Arch Immunol Ther Exp (Warsz)</i> <b>33</b> :219-240.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  <b>INFORMATION DISCLOSURE STATEMENT          BY APPLICANT</b>  (USE SEVERAL SHEETS IF NECESSARY)	ATTY. DOCKET NO. <del>NIH2981DC1CC1</del> <b>NIH298:1DC1CC1</b>	APPLICATION NO. 10/659,711
	APPLICANT Merrill et al.	
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	<b>40</b> Slopek, S. et al. 1985 "Results of bacteriophage treatment of suppurative bacterial infections. VI. Analysis of treatment of suppurative staphylococcal infections," <i>Arch Immunol Ther Exp (Warsz)</i> <b>33</b> :261-273.
	<b>41</b> Smith, H.W. et al. 1982 "Successful treatment of experimental <i>Escherichia coli</i> infections in mice using phage: its general superiority over antibiotics," <i>J. Gen. Microbiol.</i> <b>128</b> :307-318.
	<b>42</b> Smith, H.W. et al. 1983 "Effectiveness of phages in treating experimental <i>Escherichia coli</i> diarrhea in calves, piglets and lambs," <i>J. Gen. Microbiol.</i> <b>129</b> :2659-2675.
	<b>43</b> Smith, H.W. et al. 1987 "The control of experimental <i>Escherichia coli</i> diarrhea in calves by means of bacteriophages," <i>J. Gen. Microbiol.</i> <b>133</b> :1111-1126.
	<b>44</b> Soothill, J.S. 1992 "Treatment of experimental infections of mice with bacteriophages," <i>J. Med. Microbiol.</i> <b>37</b> :258-261.
	<b>45</b> Stent, G. 1963 "The Twort-D'Herelle Phenomenon," in: <u>Molecular Biology of Bacterial Viruses</u> , W.H. Freeman and Co., San Francisco and London, Chapter 1, pp. 1-21.
	<b>46</b> Vymola, F. et al. 1974 "Staphylococcal osteomyelitis" <i>Ann. N Y Acad. Sci.</i> <b>236</b> :508-514.
	<b>47</b> Zell, V.R.A. 1993 "Gentherapie, Medizin der Zukunft?" <i>Dtsch Apoth Ztg</i> <b>133</b> :19-27.

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